

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO:</b>	
<b>WAVE 1 CASES ON ATTACHED EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**PLAINTIFFS’ REPLY IN SUPPORT OF PLAINTIFFS’ MEMORANDUM OF LAW IN  
SUPPORT OF THEIR *DAUBERT* MOTION TO EXCLUDE OR, IN THE  
ALTERANTIVE, TO LIMIT THE OPINIONS AND TESTIMONY OF  
STEPHEN M. FACTOR, M.D.**

Plaintiffs hereby file Plaintiffs’ Reply in Support of Plaintiffs’ Memorandum of Law in Support of Their Daubert Motion to Exclude or, in the Alternative, To Limit the Opinions and Testimony of Stephen M. Factor, M.D.

**ARGUMENT**

Defendant agrees that expert Stephen Factor, M.D. (“Dr. Factor”) has no real experience in mesh or mesh pathology. The crux of Defendants’ argument appears to be that this significant shortcoming simply does not matter. Dr. Factor’s proposed testimony is almost solely a critique Plaintiffs’ expert Dr. Iakovlev, whose opinions focus on how mesh reacts in the human body based on his extensive experience, thorough review of hundreds of medical and scientific publications, including his own, his review of Ethicon’s internal documents, and his review of pathology slides. Thus, the very opinions Dr. Factor seeks to critique are admittedly outside the bounds of his experience. Defendants cannot avoid the reality that Dr. Factor is entirely unable to form reliable opinions that will assist the jury on the specific issues involved in this case.

Defendants cannot argue with a straight face that Dr. Factor's reliance on only three studies (out of many hundreds) somehow demonstrates that Dr. Factor's opinions - concerning the typical response to Prolene and Prolene Soft mesh - are reliable. To put it simply, both parties agree that Dr. Factor has no real experience involving polypropylene or mesh and his reliance on just three very limited studies – all by Ethicon's employees or paid consultants – somehow allows him to now offer a reliable opinion despite previously testifying that he could not opine on the expected inflammatory response associated with Prolene.<sup>1</sup>

**I. Defendant's response fails to show that Dr. Factor is qualified to render opinions in this case.**

Defendant acknowledges that Dr. Factor has no real mesh-specific experience. Def. Br. at 1 (“Dr. Factor readily admits that the bulk of his experience is not mesh specific.”). The Defendants further concede that Dr. Factor “does not seek to opine generally about mesh design or biomaterials” but in the same breadth argue that Dr. Factor's opinions “that touch on these subjects are derived from and linked to his experience and expertise with the field of pathology.” Def. Br. at 3. This argument ignores the fact that Dr. Factor admitted he has none of this experience and fails to take into account that Dr. Iakovlev's opinions are not general in nature, but are specific to polypropylene mesh and how it reacts in the human body. Dr. Factor has no experience qualifying him to critique such specific opinions.

Though Defendant points to a prior ruling by this Court to argue that this experience is not required, it fails to acknowledge that in that case the expert in question had “knowledge of and experience with pelvic mesh explants in particular, having examined fifty explant samples

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<sup>1</sup> In its response, Defendant includes reference to the purpose of rebuttal experts. Def. Br. at p. 9. Plaintiffs note that Dr. Factor was not specifically disclosed as a rebuttal expert in this case. To the extent that his testimony is permitted by this Court, it should be limited purely to rebuttal testimony.

over the past five years.” *Frankum v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 57251, \*74 (S.D. W. Va. May 1, 2015).

While Dr. Factor may have general experience in his field as a pathologist, he does not have *any* experience related to pelvic mesh. Further, regardless of the distinction Defendants attempt to make concerning the opinions offered in the *Wicker* and *Gross* cases, it is irrefutable that Dr. Factor does not know the science or medicine related to the implant of pelvic mesh devices. Pl. Br. at p. 2-5. Defendant’s assertion that Dr. Factor general experience in pathology is enough and that he does not need any mesh-related experience should be discarded by this Court entirely.

**II. Defendant fails to show that Dr. Factor used a reliable methodology to form his opinions in this case.**

While it is true that this Court has allowed other pathologists to testify in other mesh cases after determining that their opinions were based on “reliable pathology methods”, those prior cases are distinguishable from the present facts. For example, this Court allowed Dr. Trepeta to testify based on a finding that Dr. Trepeta’s methodology was reliable. In reaching its decision in that case, this Court relied on the fact that Dr. Trepeta studied over fifty mesh explant samples in his private practice over the course of five years, examined these samples under a microscope in order to reach his conclusions, largely based his opinions on his study of mesh pathology samples during his practice, studied the medical literature on mesh implantation and analyzed his findings in conjunction with this literature, and reviewed twenty-four additional pathology reports to form his opinions. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 529-530, 2014 U.S. Dist. LEXIS 155138, \*43-44 (S.D. W. Va. 2014). Dr. Factor did not rely on any past experience analyzing mesh explants, because he does not have this experience. Pl. Brf at 5.

**III. Dr. Factor Is Not Qualified To Offer Reliable Opinion Testimony Concerning the Expected and Typical INflammaotry Response to Prolene and Prolene Mesh Devices Once Implanted in the Female body.**

Dr. Factor has already admitted that he is not qualified to offer an opinion concerning the expected inflammatory response to Ethicon's Prolene and Prolene Soft mesh devices once implanted in the female body. Pl. Br. at 7. Nevertheless, the Defendants argue that Dr. Factor is qualified to offer this opinion and that it is reliable. In support of this argument, the Defendants attach three studies. The first study was publsiehd – all published by Ethicon employees or paid consultants. The first study by Elmer et al involved on just 10 women implanted with Prolift (Prolene Soft) and did not analyze *any* explanted Prolene Soft material but instead only analyzed a small amount of tissue (6mm wide) removed via a punch biopsy at an area “adjacent to the mesh-tissue interface. Def. Br. Ex. D. The Defendants also cite to Falconer et al which, just like the Elmer study, only involved 10 women implanted with TVT (Prolene). Just like the publication by Elmer, the investigators did not analyze *any* explanted TVT material but instead only analyzed a small amount of tissue (again 6 mm) removed via punch biopsy 6-8 mm lateral to the external meatus of the urethra and to a depth of 10mm. Neither of these studies looked at any explanted Prolene or Prolene Soft material and publication were by paid Ethicon consultants. Finally, the Defendants finally rely on a 91-day rat study that was conducted by Ethicon internally. Def. Br. Ex. E. This is just an abstract, not a peer-reviewed publication, only last 91 days and relates to a study of Prolene explanted from the back of rats, not from women's pelvic tissue. The Defendants' reliance on these three studies in its motion only underscores the unreliability of Dr. Factor's opinions which must be excluded.

**IV. Dr. Factor's criticisms of Dr. Iakovlev have no reliable scientific foundation, and should therefore be excluded.**

Defendant argues that Dr. Factor's opinions should not be excluded on the grounds that they criticize Dr. Iakovlev. But the problem with Dr. Factor's proffered testimony is that it includes nothing more than blanket assertions that, as discussed above, are not based on any scientific methodology or applicable experience. The issue is not that Dr. Factor does not offer an alternative; but his complete inability to reach any conclusion himself about how mesh responds in the human body. The Court should not admit such testimony. When opinions, even in the form of criticisms, have no reliable scientific basis, "[t]his *ipse dixit* does not survive Daubert's scrutiny." *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 701, 2014 U.S. Dist. LEXIS 152457, \*92 (S.D. W. Va. 2014).

**CONCLUSION**

For the reasons stated herein, Dr. Factor's testimony should be excluded in its entirety.

Dated: May 16, 2016

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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